Appendix H

Environmental Hazard Assessment and Ecological Risk Assessment Methodology

H-1. HAZARD PROFILE

The environmental hazard assessment of chemicals consists of the identification of the effects that a chemical may have on organisms in the environment. An overview of this assessment process has been reported by, for example, Smrchek and Zeeman (1998) and by Zeeman and Gilford (1993). The effects are expressed in terms of the acute and chronic toxicity of a chemical on the exposed organisms. These are generally given as either the lethal concentration (LC) or as the effective concentration (EC) that describe the type and seriousness of the effect for a known concentration of a chemical. When the effective concentrations for a range of species for a chemical are tabulated, the tabulation is called a hazard profile or toxicity profile. A more detailed discussion of a comprehensive hazard profile has been presented by Nabholz (1991). The most frequently used hazard profile for the aquatic environment consists of a set of six effective concentrations as reported by Nabholz et al. (1993a). These are:

- Fish acute value (usually a fish 96-hour LC_{50} value)
- Aquatic invertebrate acute value (usually a daphnid 48-hour LC_{50} value)
- Green algal toxicity value (usually an algal 96-hour EC_{50} value)
- Fish chronic value (usually a fish 28-day chronic value [ChV])
- Aquatic invertebrate chronic value (usually a daphnid 21-day ChV)
- Algal chronic value (usually an algal 96-hour NEC or GMATC value for biomass)

For the acute values, the LC_{50} (lethality or mortality) (EC_{50}) (non-lethal/lethal effects) refers to the concentration that results in 50 percent of the test organisms affected at the end of the specified exposure period in a toxicity test. The chronic values represent the concentration of the chemical that results in no statistically significant sublethal effects on the test organism following an extended or chronic exposure.

The hazard profile can be constructed using effective concentrations based on toxicity test data (with measured test chemical concentrations) or estimated toxicity values based on structure activity relationships (SARs). The measured values are preferred because they are based on actual test data, but in the absence of test data SAR estimates, if available for the chemical class, can be used. Thus the hazard profile may consist of only measured data, only predicted values, or a combination of both. Also, the amount of data in the hazard profile may range from a minimum of one acute or chronic value to the full compliment of three acute values and three chronic values.

In the absence of measured toxicity values, estimates of these values can be made using SARs. SAR methods include quantitative structure activity relationships (QSARs), qualitative SARs, or use of the chemical analogs. The use of SARs by OPPT has been described (Clements, 1988; Clements, 1994). The use and application of QSARs specifically for the hazard assessment of TSCA new chemicals has been presented (Clements et al., 1993a). The development, validation, and application of SARs in OPPT have been presented by OPPT staff (Zeeman et al., 1993b; Boethling, 1993; Clements et al., 1993b; Nabholz et al., 1993b; Newsome et al., 1993 and Lipnick, 1993).

The predictive equations (QSARs) are used in lieu of actual test data to estimate a toxicity value for aquatic organisms within a specific chemical class. A total of 140 have been listed (Clement et al., 1995; Smrchek and Zeeman, 1998). Although the equations are derived from correlation and linear regression analysis based on measured data, the confidence intervals associated with the equation are not used to provide a range of toxicity values. Even with measured test data, the use of the confidence limits to determine the range of values is not used.

H-2. DETERMINATION OF CONCERN CONCENTRATION

Upon completion of a hazard profile, a concern concentration (CC) is determined. A concern concentration is that concentration of a chemical in the aquatic environment, which, if exceeded, may cause a significant risk to aquatic organisms. Conversely, if the CC is not exceeded, the assumption is made that probability of a significant risk occurring is low and no regulatory action is required. The CC for each chemical is determined by applying assessment factors (AsF) (U.S. EPA, 1984) or uncertainty factors (UF) (Smrchek et al., 1993) to the effect concentrations in the hazard profile.

These factors incorporate the concept of the uncertainty associated with: 1) toxicity data, laboratory tests versus field tests, and measured versus estimated data; and 2) species sensitivity. For example, if only a single LC_{50} value for a single species is available, there are several uncertainties to consider. First, how reliable is the value itself? If the test were to be done again by the same laboratory or a different laboratory, would the value differ and, if so, by how much? Second, there are differences in sensitivity (toxicity) among and between species that have to be considered. If the species tested the most or the least sensitive? In general, if only a single toxicity value is available, there is a large uncertainty about the applicability of this value to other organisms in the environment and a large assessment factor, i.e., 1000, is applied to cover the breadth of sensitivity known to exist among and between organisms in the environment. Conversely, the more information that is available results in more certainty concerning the toxicity values and requires the use of smaller factors. For example, if toxicity values are derived from field tests, then an assessment factor of 1 is used because tests measure chemical effects on field organisms.

Four factors are used by OPPT to set a CC for chronic risk: 1, 10, 100, and 1000. The factor used is dependent on the amount and type of toxicity data contained in the hazard profile and reflects the amount of uncertainty about the potential effects associated with a toxicity value. In general, the more complete the hazard profile and the higher the quality of the generated toxicity data, the smaller a factor that is used. The following discussion describes the use and application of uncertainty or assessment factors.

1. If the hazard profile only contains one or two acute toxicity values, the concern concentration is set at 1/1000 of the acute value.

2. If the hazard profile contains three acute values (called the base set), the concern concentration is set at 1/100 of the lowest acute value.

3. If the hazard profile contains one chronic value, the concern concentration is set at 1/10 of the chronic value if the value is for the most sensitive species. Otherwise, it is 1/100 of the acute value for the most sensitive species.

4. If the hazard profile contains three chronic values, the concern concentration is set at 1/10 of the lowest chronic value.

5. If the hazard profile contains a measured chronic value from a field study, then an assessment factor of 1 is used.

H-3. HAZARD RANKING

Chemicals can be also ranked by their hazard concern levels for the aquatic environment. This ranking can be based upon the acute toxicity values expressed in milligrams per liter (mg/L). The generally accepted scoring used by OPPT is as follows (Smrchek et al., 1993; Wagner et al., 1995):

High Concern (H)	≤ 1
Moderate (or Medium) Concern (M)	> 1 and ≤ 100
Low Concern (L)	> 100

This ranking can also be expressed in terms of chronic values as follows:

High Concern (H)	≤ 0.1
Moderate (or Medium) Concern (M)	> 0.1 and ≤ 10.0
Low Concern (L)	> 10.0

Chronic toxicity ranking takes precedent over the acute ranking.

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